



NOBAMED Paul Danz AG

PFLEGEKITTEL

REF 664105

Product Description, Intendend use, Application

The protection gown, **size M**, is made of nonwoven. Its front and arms are impermeable to liquid, blood, and viruses. The yellow protection gown is open in the back and has knitted, elastic cuffs as well as ribbons for tie-fastening in the waist and at the collar. The cuffs allow for a tight fit of disposable gloves. Due to the breathable material of the backside, the product is comfortable to wear. The yellow colour of the protection gown can be used for the assignment to specific sectors for example when nursing MRSA and VRSA patients. The use of the gown reduces the spread of germs and contaminations during nursing or medical activities. The gown is for single use.

Composition

Polypropylene (SPP), Polyethylene (front and arms)

Cuffs: mixture of polyester and cotton

Contraindications

The product should not be used in the case of a known allergy against the material.

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulatory Requirements, Common Standards

Medical Device according to

MDD 93/42/EEC, MDR (EU) 2017/745.

The product does not contain dangerous toxic substances according to REACH.

The impermeability of the protection gown's front and arms against liquids, blood, and viruses has been proven in accordance with ASTM F 1670 "Synthetic Blood Test", ASTM F 1671 "Viral Penetration Test", ASTM F 739 "Test for Permeation of Liquids", ASTM F 903 "Test of resistance to penetration by liquids", AAMI PB 70- AATC 127 "Liquid barrier performance".

Packaging

Primary packaging: PE- bag

Secondary packaging: carton
made of cellulose

Symbols used in labelling

Explanations at www.nobamed.com



Storage and Transport

Dry and dustfree.

Single use device

Reusing aa single use medical device can lead to microbiological danger. Reprocessing, for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.